EDITORIAL

On-site surgical standby for percutaneous coronary intervention: a thing of the past?

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Is the requirement for onsite surgical back-up in centres performing percutaneous coronary intervention still relevant today? *See article on page 335.*

In this edition of *Heart*, Carlsson *et* al[1] report on the outcome of 8838 percutaneous coronary intervention (PCI) procedures in 14 Swedish centres without surgical back-up in comparison with 25 525 procedures in 10 hospitals with surgical back-up. They conclude that there were no differences in outcomes (with regard to mortality at least) and that current guidelines should no longer insist on onsite surgical backup for PCI. As the authors point out, the debate on this issue has raged for years, and some of the arguments for mandating onsite surgery have indeed become weaker over time.

Early national guidelines mandated surgical standby mainly because of the need for emergency coronary artery bypass grafting (CABG) in >5% of cases in the early days of angioplasty.[2] This is clearly no longer the case. The use of stents, glycoprotein IIb/IIIa inhibitors and pretreatment with dual antiplatelet therapy has seen a year-on-year decrease in the need for emergency surgery. In the annual reports from the British Cardiovascular Intervention Society (BCIS), the need for emergency surgery fell from 2% in 1992 to 0.12% in 2005.[3]

STENTS NOT ALWAYS THE ANSWER

However, the need for emergency surgery remains. Not all problems can be resolved with stents. Moreover, there are occasional mishaps with stents requiring surgical solutions. Covered stents cannot be used in all cases of tamponade secondary to coronary perforation. Right ventricular perforation secondary to adjunctive pacing electrodes can also lead to the need for surgical bailout (especially in the milieu of strong antiplatelet therapy). It is noteworthy that some of these cases may not be identified in national audit databases asking only about the need for ''emergency CABG''. Although emergency surgery probably saves lives, in general, it is indicative of a poor outcome with an increased risk of mortality or non-fatal myocardial infarction.[4 5] In highly compromised patients, it is required without delay. Some patients with multivessel disease requiring emergency surgery may require crash bypass and such patients are unlikely to survive transfer.[6]

Emergency surgery is needed more in urgent and emergency cases, with rates of 0.1% for stable elective cases, 0.13% in unstable angina, 0.3% in primary PCI and 0.6% in rescue angioplasty in the latest BCIS report.[3] Patients undergoing angiography in the context of ST elevation may require surgery as a complication of angioplasty, but more commonly require surgery because of ''surgical disease'',[5] and occasionally this is required on an emergency basis. In the UK, against the evidence, patients are rarely referred for emergency surgery in the context of cardiogenic shock (except for acute mechanical problems such as a ventricular septal defect or mitral regurgitation).

UK GUIDELINES

UK guidelines on the subject of surgical cover for PCI have softened from a statement that on-site surgery is the ''strongly preferred option'' to accepting that good practice can be achieved at off-site centres. The guidelines have been reworded to ''adequate provision for cardiac surgery is still a prerequisite to safe PCI'' and recommend that all PCI centres should be in a position to establish cardiopulmonary bypass within 90 min of the referral having been made to the surgical service.[7 8] Despite the case that is made to develop off-site PCI for the management of ST elevation myocardial infarction,[9] the US guidelines remain steadfast, stating that performance of elective PCI in a setting without immediately available on-site cardiac surgery potentially compromises patient safety and is not recommended.[10]

Given the US position, why are the UK guidelines different? One could start by asking what the need is (or was) for developing PCI services in non-surgical centres. The accusation that some sites started off-site PCI activity simply as a means of bringing business to their hospitals has been implied.[11] Probably the most common reason in the UK was an inability of regional on-site PCI centres to cope with the flow of traffic as the indications for PCI have expanded, associated with a lack of planning on a regional basis. The argument was that the infrequent difficulties associated with surgical bailout would be more than compensated for by the reduction in morbidity and mortality associated with waiting lists. However, waiting lists, even in the UK, are far less of a problem than they used to be. It was also pointed out that although there would be inherent delays in transferring patients from off-site centres to emergency surgery, on-site centres themselves were no quicker at doing this (at least ''on average''). The greatest time delay in emergency

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Abbreviations: ACS, acute coronary syndrome; BCIS, British Cardiovascular Intervention Society; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; PPCI, primary PCI

surgery was usually caused by a wait for the surgical team to be in a position to operate on the patient rather than the transfer time from one hospital to another.[12] Nowadays, some hospitals believe that the introduction of primary PCI (PPCI) as a treatment for acute ST elevation myocardial infarction is another driver for local delivery of treatment.[13] The counter to this is to arrange ambulance services appropriately to transfer patients directly to the nearest high-volume heart attack centre capable of providing PPCI.[14]

In the UK, there has been a considerable move to expand local services with a major growth in ''diagnostic-only'' centres. The aim has been to provide the diagnostic investigation locally while simultaneously freeing up space and time for regional centres to increase their capacity for angioplasty and other services such as complex electrophysiology. Those who frown at the strategy of separating diagnostic and PCI services cite the growth in follow-on angioplasty as being more efficient and preferable to patients, and a concern that the diagnostic centre might then want to develop low-volume PCI activity. Indeed, this has been happening. Outcomes are better in high-volume centres with high-volume operators, even in the stent era.[15 16] Whatever one's view, there are now 54 PCI centres with on-site surgery and 29 without (representing 35%).[3]

INVESTIGATING PATIENTS WITH ACS

Most of the new diagnostic centres started performing elective cases only, transferring patients with acute coronary syndromes (ACS) for investigation and treatment at the regional on-site centres. Over time, however (and stimulated by recent changes in UK central healthcare policy), patients with ACS are now sometimes being investigated locally. A requirement to perform sufficient angiograms to comply with criteria laid down by local health authorities has almost certainly influenced this change of practice in some hospitals. The clinical argument proposed in favour of this is an improvement in triage for those requiring coronary surgery and for those in whom medical treatment is chosen. The argument against is the need for a ''double-stick'' for patients selected for PCI. This disadvantage for patients treated by angioplasty (most of such patients) is a clear argument for transferring hot cases to a PCI centre. If diagnostic angiography is to be undertaken on patients with ACS in non-PCI centres, then the use of risk assessment scores, such as the Thrombolysis In Myocardial Infarction score,[17] might allow appropriate identification of low-risk patients with a smaller chance of requiring revascularisation. However, this practice does seem to have been a driver in some community hospitals to build up local angioplasty services.

There has been a move then from providing a diagnostic service on elective patients, to investigating those with ACS, to providing off-site PCI. Once such a service is treating patients with unstable angina and non-ST elevation myocardial infarction, why not make the move to PPCI? The message is clear that call-to-balloon and door-to-balloon times should be kept to a minimum and although transfer to a PCI centre provides better outcomes than locally delivered thrombolysis, it is also clear that longer delays related to transfer have a negative effect on PPCI outcomes.[18] Local delivery of PPCI can be delivered in off-site centres with good results.[19] This and other published experiences stimulate the move to provide more local services rather than to expand already stretched regional on-site centres. However, the volume of activity by both centre and operator are just as important for best outcomes in PPCI as with elective work.[20] Moreover, in the UK at least, most patients live within an acceptable ambulance journey from current PCI centres. The requirements for providing a national PPCI service in the UK are currently under review by a joint working group between the Department of Health, BCIS and the British Cardiovascular Society (the so-called National Infarct Angioplasty Project). The US guidelines consider the possibility of PPCI being performed in an off-site centre but only by experienced teams, with appropriate planning, running a 24 h service and with a proven plan for rapid transfer to a cardiac surgery operating room in a nearby hospital, with appropriate haemodynamic support capability for transfer to surgery. If these criteria cannot be met, these guidelines suggest that PPCI should not be performed. These criteria, based on evidence and common sense, should apply to all centres wishing to perform PPCI.

BEST PRACTICE

Best practice in off-site PCI comes from units that have carefully planned and developed the service in collaboration with a surgical unit.[21 22] Agreed clinical protocols and regional coordination are essential. Ad hoc arrangements that might be guided by motives other than the optimal treatment of the patients should be strongly discouraged. Moving from publications on best practice to surveys of what is actually happening provides sobering reading. Wennberg *et* al[23] have shown that although outcomes for primary angioplasty have been acceptable in some off-site centres, the same centres have worse outcomes in the non-emergency population of patients compared with higher-volume on-site centres.

In Carlsson *et al*'s[1] study, we cannot tell the driving forces behind the development of off-site services. Interestingly, in Sweden, off-site centres seem to perform PCI on a population with a higher demographic risk profile, although they perform proportionately more elective work and less PCI in the context of ST elevation myocardial infarction. Whether this reflects different populations or a different angioplasty practice is not clear. It is also not evident why off-site centres perform proportionately less PCI in the context of ST-segment elevation myocardial infarction. It might be that PPCI is only carried out in some of these centres, but it might reflect lower volumes of PPCI in all the smaller centres. The information provided does suggest a degree of case selection in the off-site centres (which of course may be the key to their success).

Their unadjusted data suggest that PCI-related mortality is lower in the off-site centres, but this seems to be at odds with the fact that 30-day mortality is numerically lower in the on-site centres in each of the patient subgroups. Moreover, they do not clarify the completeness of data capture. Comparing unadjusted long-term mortality results for the two services is slightly misleading. Moreover, although they go on to perform multivariate analysis, they do not state how they chose the variables included in analysis. The lack of a number of key clinical variables might have profoundly altered their conclusions.

Their study shows that emergency CABG is used less often by the off-site centres, but it is not clear whether this is driven predominantly by the lack of timely surgery in certain situations or by fewer PCI complications. Those not referred for emergency CABG (but who might have been in different circumstances) may be hidden in the analysis. We cannot tell whether any patient died or had avoidable ventricular damage because of the lack of timely surgery. Although they base their argument predominantly on mortality, it is hard to differentiate units based on mortality alone, given that it is so low, especially with non-emergency patients. Risk-adjusted event-free survival may be a better measure (taking into account other end points) and although they have attempted this, the completeness of the data collection is unclear.

Notwithstanding these deficiencies, this Swedish collaborative approach is to be congratulated on providing information that encourages a sensible expansion of off-site PCI centres. Wherever one stands on the various arguments, it is clear that any such service development should be planned on a regional

basis. As with all facets of clinical activity, there is a need for an effective ''clinical network''. Such networks need a degree of authority and the ability to persuade its constituent partners that developments must be on a sustainable basis. In this context, new PCI centres should emerge only after regional discussion and with a strategic plan created in partnership with the surgical centres, healthcare purchasers as well as input from those who need the service—the patients themselves. The questions that should be asked are:

- What is the expected need for PCI in the region over the next few years?
- If growth is inevitable, how best can this be achieved?
- Can regional services be redesigned to allow current regional high-volume centres to expand their services?
- If capital expenditure is needed for an expansion of infrastructure, what options are available?
- If the current on-site centre cannot expand, and if a decision is made to develop an off-site PCI centre, which is the community hospital best placed to take on this workload?
- How can the current regional centre help the new centre to develop?
- What clinical protocols are in place to achieve best results?
- Will the off-site centre provide a comprehensive service from the start or will it start with elective cases only and then change slowly over time as experience and infrastructure develops?
- Are the clinical protocols and the timing of changes in protocols agreed by all parties?
- Which sites should provide primary angioplasty services?
- What on-call arrangements have been designed to ensure around-the-clock services?
- Can a potential new centre achieve the staffing levels needed to sustain the programme in a meaningful timeframe?
- What arrangements will be in place for the care of those needing emergency transfer from the community hospital to the regional centre (and back again)?
- Will a new centre provide value for money?

Where such strategic thinking does not take place, the possibility remains that centres develop services for the wrong reasons, and that patients are faced with an apparent benefit of a local service, but with the downside of the service being delivered by a small centre with few operators, few support staff, performing a small number of cases, with results that are not as good as in other centres. It is clearly essential that any such growth must be associated with an honest appraisal of clinical results, which in the UK means participation in the BCIS-driven collection of information on all patients undergoing PCI, through the Central Cardiac Audit Database (http://www.ccad.org.uk).

In certain European countries, PCI centres have truly grown according to the regional need with a degree of consensus and control which decides that once a regional centre is saturated with no room to expand, or because of geographical considerations, a new centre is established with assistance from the regional centre. Best practice demands a collaborative approach, with sharing of clinical information and electronic image transfer links between the centres, so that the smaller units can share cases with colleagues at the surgical centre. Results should be carefully audited. Does such a mature network approach exist elsewhere? Growth that is driven by the ambitions of individual centres, with collusion from hospital management and healthcare purchasers keen on reducing costs but without taking into account clinical outcomes, cannot be justified. Continuing development of services on a regional basis may demand some rationalisation of the current national status quo, and may be spearheaded by the concept of infarct centres.

Whatever services are provided, the situation must be inherent in informed consent for procedures. Even with today's techniques, patients must be told of the morbidity and mortality associated with PCI, and the risks quoted should reflect their individual clinical scenario. This should include a quoted risk of requiring emergency surgery. Moreover, for off-site centres, patients should be told of the process for emergency transfer for surgery should it be needed.

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